



UNITED STATES PATENT AND TRADEMARK OFFICE

Commissioner for Patents
United States Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450
www.uspto.gov

KING & SPALDING
1185 AVENUE OF THE AMERICAS
NEW YORK NY 10036-4003

MAILED

OCT 12 2010

In re Patent of Ohta et al. : OFFICE OF PETITIONS
Patent No. 7,342,014 :
Application No. 10/773,344 : ON APPLICATION FOR
Filed: February 9, 2004 : PATENT TERM ADJUSTMENT
Atty Docket No. 17620- :
105007US1 :
Title: DIAMINE DERIVATIVES :

This is in response to the "REQUEST FOR RECONSIDERATION OF DISMISSAL OF PETITION UNDER 37 C.F.R. § 1.183 AND OF DISMISSAL OF REQUEST FOR RECONSIDERATION OF PATENT TERM ADJUSTMENT UNDER 37 CFR § 1.705(d)," filed on June 1, 2010. Patentees petition under 37 C.F.R. § 1.183 for suspension of the requirement under 37 C.F.R. § 1.705(d) that any request for reconsideration of the patent term adjustment indicated in the patent must be filed within two months of the date the patent issued. Further, patentees request that the patent term adjustment be corrected from three hundred fifty-seven (357) days to seven hundred fifty-three (753) days.

The petition pursuant to 37 C.F.R. § 1.183 is **DISMISSED**.

The petition pursuant to 37 C.F.R. § 1.705(d) is **DISMISSED AS UNTIMELY FILED**.

Any request for reconsideration, whether directed to the decision on petition under 37 CFR § 1.183 or to the decision on the request under 37 CFR 1.705(d), must be filed within two months of the mailing date of this decision. Extensions of time under 37 C.F.R. § 1.136 are NOT permitted. See 37 CFR § 1.181(f).

RELEVANT STATUTE AND RULES

35 U.S.C. § 154(b)(3)(B) sets forth, *in toto*:

Under the procedures established under subparagraph (A), the Director shall-

(i) make a determination of the period of any patent term adjustment under this subsection, and shall transmit a notice of that determination with the written notice of allowance of the application under section 151; and

(ii) provide the applicant one opportunity to request reconsideration of any patent term adjustment determination made by the Director.

37 CFR § 1.183 sets forth, *in toto*:

In an extraordinary situation, when justice requires, any requirement of the regulations in this part which is not a requirement of the statutes may be suspended or waived by the Director or the Director's designee, *sua sponte*, or on petition of the interested party, subject to such other requirements as may be imposed. Any petition under this section must be accompanied by the petition fee set forth in § 1.17(f).

37 CFR § 1.705 sets forth, *in pertinent part*:

If there is a revision to the patent term adjustment indicated in the notice of allowance, the patent will indicate the revised patent term adjustment. If the patent indicates or should have indicated a revised patent term adjustment, any request for reconsideration of the patent term adjustment indicated in the patent must be filed within two months of the date the patent issued and must comply with the requirements of paragraphs (b)(1) and (b)(2) of this section. Any request for reconsideration under this section that raises issues that were raised, or could have been raised, in an application for patent term adjustment under paragraph (b) of this section shall be dismissed as untimely as to those issues.

OPINION

On March 11, 2008, the above-identified application matured into U.S. Patent No. 7,342,014 with a revised patent term adjustment of 357 days. No request for reconsideration of the patent term adjustment indicated in the patent was filed within two months of the date the patent issued.

A request for reconsideration of the patent term adjustment indicated in the patent under 37 CFR 1.705(d) and a petition under 37 CFR 1.183, both filed on February 2, 2009, were dismissed on March 30, 2010.

The present reconsideration petitions were filed on June 1, 2010, which was the first business day after the May 30, 2010 two month deadline to request reconsideration.

Having considered patentees' petition, it is concluded that in this instance waiver of the requirement that the application for patent term adjustment be filed within two months of the issuance date of the patent is not appropriate. Patentees have not shown that the circumstance of the failure to comply with the time period for filing an application for patent term adjustment set forth in 37 CFR 1.705(d), is an extraordinary situation for which justice requires waiver.

By the express provisions of 37 CFR 1.705(d), a request for reconsideration of patent term adjustment must be filed within two months of the date the patent issued. It is undisputed that no such request for reconsideration was filed by May 11, 2008, the date two months from the date this patent issued, March 11, 2008.

35 U.S.C. 154, requires the Office to provide the applicant one opportunity to request reconsideration of any patent term adjustment determination made by the Director, authorizes the Director to establish the procedures for requesting such reconsideration. Those procedures¹ include 37 CFR 1.705(d). 37

¹ 35 U.S.C. § 154(b)(3) provides that the USPTO shall: (1) prescribe regulations establishing procedures for the application for and determination of patent term adjustments under 35 U.S.C. § 154(b); (2) make a determination of any patent term adjustment under 35 U.S.C. § 154(b) and transmit a notice of that determination with the notice of allowance under 35 U.S.C. § 151; and (3) provide the applicant one opportunity to request reconsideration of any patent term adjustment determination. Pursuant to the mandate and authority in 35 U.S.C. § 154(b)(3), the USPTO promulgated 37 C.F.R. § 1.705, which provides that: (1) the notice of allowance will include notification of any patent term adjustment under 35 U.S.C. § 154(b) (37 C.F.R. § 1.705(a)); (2) any request for reconsideration of the patent term adjustment indicated in the notice of allowance (except as provided in 37 C.F.R. § 1.705(d)) must be by way of an application for patent term adjustment filed no later than the payment of the issue fee and accompanied by (inter alia) the fee set forth in 37 C.F.R. § 1.18(e) (37 C.F.R. § 1.705(b)); and (3) if the patent indicates or should have indicated a revised patent term adjustment, any request for reconsideration of the patent term adjustment indicated in the patent must be filed within two months of the date the patent issued.

CFR 1.705(d) provides an avenue before the Office for requesting reconsideration of the Office's determination of patent term adjustment indicated in the patent. Moreover, §1.705(d) states that "any request for reconsideration of the patent term adjustment indicated in the patent must be filed within two months of the date the patent issued and must comply with the requirements of paragraphs (b)(1) and (b)(2) of this section."

Patentees have not shown that any extraordinary situation prevented them from timely filing a petition under 37 CFR 1.705(d). Under these circumstances, justice does not require that patentees' failure to timely file an application for patent term adjustment be treated any differently than any other patentee. Waiver of the requirement is not warranted.

The facts of record do not support an extraordinary situation. There is nothing extraordinary about a registered practitioner who is faced with a deadline, and has limited time to submit a paper to the Office to preserve his rights. Moreover, there is nothing extraordinary about a practitioner who failed to act in concert with published regulations.

The Office concludes that this situation does not constitute an extraordinary situation such that justice requires the waiver of the Rule.

As there is no dispute that this application for PTA was filed more than two months after the patent issued and it has been concluded that waiver of the requirement is not warranted, it is appropriate to dismiss this application for patent term adjustment as being untimely filed. On February 1, 2010, the USPTO published a Federal Register notice that, *inter alia*, announced a limited waiver of the two-month deadline for filing a petition for reconsideration of a PTA determination under 37 CFR § 1.705(d). See *Interim Procedure for Patentees to Request a Recalculation of the Patent Term Adjustment to Comply with the Federal Circuit Decision in Wyeth v. Kappos Regarding Overlapping Delay Provisions of 35 U.S.C. § 154(b)(2)(A)*, 75 Fed. Reg. 5043 (Feb. 1, 2010) (notice). Specifically, patent owners were permitted to request recalculation of a patent's PTA in view of the Federal Circuit decision *Wyeth v. Kappos*, 591 F.3d 1364 (Fed. Cir. 2010) up to 180 days after the grant of the patent. The USPTO determined not to accept any requests for PTA recalculation initially filed more than 180 days after patent


grant, however, in view of the statutory judicial-review provisions of 35 U.S.C. sec. 154(b)(4), which require that any civil action to challenge the USPTO's PTA determination be brought within 180 days of patent grant. The USPTO believes that the statutory 180-day period for seeking court review of the USPTO's PTA determinations, particularly in view of the six-year statute of limitations that otherwise is applicable for actions under the Administrative Procedure Act, indicates a congressional intent that PTA issues be resolved shortly after a patent issues. The USPTO does not consider it likely that Congress created a scheme under which the time period to seek initial USPTO review of a PTA determination extends beyond the time period provided for a dissatisfied patentee to seek judicial review of the USPTO's PTA determination. Thus, the USPTO believes that the 180-day period in 35 U.S.C. sec. 154(b)(4) represents the outer limit on the USPTO's ability to conclude its PTA determination.

It is noted that the first petition under 37 CFR 1.705(d) was filed 329 days after the patent issued.

In view thereof, it is concluded that the initial determination of Patent Term Adjustment of three hundred fifty-seven (357) days will not be reconsidered.

The Office acknowledges previous submission of the \$200.00 fee set forth in 37 CFR 1.18(e) and the \$400.00 fee set forth in 37 CFR 1.17(f). No additional fees are required.

Telephone inquiries regarding this decision should be directed to the undersigned at (571) 272-3230.


Shirene Willis Brantley
Senior Petitions Attorney
Office of Petitions